

510(k) SUMMARY

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| Submitter | ANTHOGYR SAS 2237, avenue Andre Lasquin SALLANCHES, FRANCE 74700 Registration Number: 8020776 |
| Contacts | Ms Thérèse CANDAU m.candau@anthogyr.com Phone (33) (0)4 50 58 02 37 Fax (33) (0)4 50 93 78 60 Regulatory: Dr Isabelle DRUBAIX (PhD) IDEE CONSULTING idrubaix@nordnet.fr |
| Trade Name | AXIOM® REG |
| Classification Name | ENDOSSEOUS DENTAL IMPLANT ENDOSSEOUS DENTAL ABUTMENT |
| Class | II |
| Product Code | DZE NHA |
| CFR section | 21CFR 872.3640 |
| Device panel | DENTAL |
| Legally marketed predicate devices | AXIOM dental Implant system K101913 Nobel Speedy Replace K050406 Dentsply Friadent implant system - XiVE S Plus K073075 Dentsply Ankylos C/X K083805 |
| Description | <p>The AXIOM® REG implant system has been designed in order to enhance the functional and aesthetic integration of implant supported restorations. The file concerns the expansion of prosthetic components and surgical instrumentation and also the implants of the AXIOM® REG.</p> <p>Any abutment can be assembled on any AXIOM® REG implant thanks to its unique prosthetic connection, regardless of the implant diameter chosen.</p> <ul style="list-style-type: none"> - Implants <p>Replacement of a missing root for placement of a dental restoration. The implant is screwed in the upper or lower jaw.</p> <p>Material: Ti6Al4V</p> <p>Surface treatment: BCP®</p> <p>Dimensions: Ø3.4 mm, length: 16-18 mm Ø 4.0 mm, length: 16-18 mm</p> <ul style="list-style-type: none"> - Conical abutments <p>Provide support for a permanent restoration, for multiple screw-retained prosthesis and screw-retained bar and brace</p> <p>Material: Ti6Al4V</p> <p>Dimensions: gingival height: 4.5 mm angle: 18-30°</p> <p>Rotational and non rotational abutments.</p> <ul style="list-style-type: none"> - Aesthetic titanium abutments <p>Provide support for a permanent restoration, single and multiple-unit cemented restoration.</p> <p>Material: Ti6Al4V</p> <p>Dimensions: Ø3.4 mm; gingival height: 2.5-4.5 mm; angle: 7-15°</p> |

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| | <p>Ø4.0 mm; gingival height: 0.75-4.5 mm; angle: 0-23° Ø5.0 mm; gingival height: 0.75-4.5 mm; angle: 0-23° Ø6.0 mm; gingival height: 1.5-4.5 mm; angle: 0-15°</p> <ul style="list-style-type: none"> - Standard angulated titanium abutments <p>Provide support for a permanent restoration</p> <p>Material: Ti6Al4V</p> <p>Dimensions: Ø4.0 mm; gingival height: 1.5-3.5 mm; angle 15-23° Ø5.0 mm; gingival height: 1.5-3.5 mm; angle 15-23°</p> <ul style="list-style-type: none"> - Temporary abutments <p>Provide support for a temporary restoration</p> <p>Material: Ti6Al4V</p> <p>Dimensions: Ø3.4 mm; height: 1.5-4.5 mm Ø4.0 mm; height: 0.75-4.5 mm Ø5.0 mm; height: 0.75-4.5 mm Ø6.0 mm; height: 1.5-4.5 mm</p> <ul style="list-style-type: none"> - Healing screws and healing screws flat <p>Sealing of implant conical connection during bone healing. Prepare gingiva to the permanent restoration shape.</p> <p>Material: Ti6Al4V</p> <p>Dimensions: Ø3.4 mm; height: 4.5 mm Ø4.0 mm; height: 0.75-4.5 mm Ø5.0 mm; height: 0.75-4.5 mm Ø6.0 mm; height: 4.5 mm</p> <p>Dimensions (flat version): Ø3.4 mm; height: 1.5-4.5 mm Ø4.0 mm; height: 0.75-4.5 mm Ø5.0 mm; height: 0.75-4.5 mm Ø6.0 mm; height: 1.5-4.5 mm</p> <ul style="list-style-type: none"> - Pacific system <p>Ensure passive fit between the conical abutment and the framework. Reserved exclusively for multiple or full-arch screw-retained prostheses on straight conical abutments.</p> <p>Materials: Ti6Al4V, PMMA</p> <ul style="list-style-type: none"> - Temporary cap and protecting cap <p>Give the negative shape of the permanent abutment for the design and realization by casting (lost wax process) of a dental restoration</p> |
| Indications for use | <p>Anthogyr AXIOM® REG implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures.</p> <p>The Axiom dental system is indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading.</p> <p>Prefabricated components are intended for use as accessories to dental implants to support implant-supported restorations.</p> |

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| Performance data | <p>AXIOM® Endosseous dental implant systems (AXIOM® REG) conforms to Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff Document issued on May 12, 2004.</p> <p>A fatigue testing according to the standard NF EN ISO 14801 (2007) has been performed for added devices.</p> <p>Results demonstrate comparable mechanical properties to the predicate device. No clinical data has been presented.</p> |
| Substantial equivalence | <p>ANTHOGYR Endosseous dental implant systems (AXIOM® REG) is substantially equivalent to its predicate devices in terms of intended use, material, design, mechanical properties and function. Non clinical performance testing according to special control demonstrate that ANTHOGYR Endosseous dental implant system (AXIOM® REG) is as safe, as effective, and performs as safely and effectively as its predicate devices.</p> |
| Preparation date | February 19 th , 2014 |



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Ms. Therese Candau
Regulatory Affairs Engineer
Anthogyr SAS
2237 Avenue Andre Lasquin
Sallanches, FRANCE 74700

Re: K131066
Trade/Device Name: Axiom REG
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 15, 2014
Received: January 22, 2014

Dear Ms. Candau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for
Kwame O.
Ulmer-S.

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

510(k) Number (if known)

K131066

Device Name

AXIOM REG

Indications for Use (Describe)

Anthogyr AXIOM® REG implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for stabilization of removable prostheses or fixation of single tooth restorations or partial dentures. The Axiom dental system is indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading. Prefabricated components are intended for use as accessories to dental implants to support implant-supported restorations.

Type of Use (Select one or both, as applicable)

 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Mary S. Runner -S
 2014.02.21
 09:42:24-05'00'

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